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SEP 11 2009

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
PiGalileo Screw Targeting System V1.1

Contact Person and Address
Regina Holmes
Regulatory Affairs Specialist
Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116
(901) 399-6538

Date of Summary: 08/12/2009

Name of Device: Smith & Nephew PiGalileo Screw Targeting System V1.1
Common Name: Computer Assisted Surgery System

Device Description
The PiGalileo Screw Targeting System is a computer controlled electromagnetic tracking system. It assists the surgeon in locating and positioning screws in an intramedullary nail implant during orthopedic trauma surgery.

The link between the sterile surgical area (patient) and the instrument system is provided through an electromagnetic tracking system. Electromagnetic spatial measurement systems determine the location of instruments that are embedded with sensor coils. When the sensor-embedded instrument is placed inside controlled, varying magnetic fields, voltages are induced in the sensor coils. These induced voltages are used by the measurement system to calculate a 3D virtual position of the instrument. Because the magnetic fields are of a low field strength and can safely pass through human tissue, location measurement of an object is possible without the line-of-sight constraints of an optical spatial measurement system that requires a camera.

Device Classification
21 CFR 882.4560 Stereotaxic Instrument – Class II

Indications for Use
The Smith & Nephew PiGalileo Screw Targeting System is intended to be an intraoperative image guided localization system. It is a computer assisted orthopedic surgery tool to aid the surgeon with drill positioning for screws during intramedullary nail implantation. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing intraoperatively obtained electromagnetic tracking data. The Smith & Nephew PiGalileo Screw Targeting System V 1.1 is indicated for long bone fractures treated with intramedullary nails in which the use of stereotactic surgery may be appropriate.

Substantial Equivalence Information
The overall design of the PiGalileo Screw Targeting System V1.1 is substantially equivalent to the previously cleared device listed below:

Manufacturer	Description	510(k)	Clearance Date
Smith & Nephew, Inc.	PiGalileo Screw Targeting System V1.0	K090420	10/29/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 11 2009

Smith & Nephew
% Ms. Regina Holmes
Regulatory Affairs Specialist
1450 East Brooks Road
Memphis, Tennessee 38116

Re: K092497
Trade/Device Name: PiGalileo Screw Targeting System V1.1
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instruments
Regulatory Class: II
Product Code: OLO
Dated: August 12, 2009
Received: August 14, 2009

Dear Ms. Holmes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: PiGalileo Screw Targeting System V1.1

Indications for Use:
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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R. Cohen for max

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092497